H0127 - High Priority Medical Device Alert

Medical Device Hazard Report

Updated: October 14, 2010

UMDNS Terms:
- Ventilators, Intensive Care [17429]
- Ventilators, Intensive Care, Adult [18792]
- Ventilators, Intensive Care, Neonatal/Pediatric [14361]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- Pulmonology/Respiratory Therapy

Geographic Regions:
- Worldwide

MAQUET—Servo-i Ventilators: Breathing Circuit Support Arm May Restrict Gas Flow to Patient

Product Identifier:
Servo-i Ventilators *[Capital Equipment]*

Manufacturer: Maquet Inc A Getinge Group Co [336117], 45 Barbour Pond Dr, Wayne, NJ 07470, United States (U.S. distribution); MAQUET Nordic AB A Getinge Group Co [439169], Rontgenvagen 2, S-171 95 Solna, Sweden (international distribution)

Summary: When mounted on the same side as the inspiratory port, the breathing circuit support arm used with the above ventilators can be positioned in such a way that it compresses the circuit's inspiratory limb, restricting gas flow to the patient. This problem is possible only on the mobile cart configuration. Users can avoid this problem by securing the arm above the port or by mounting it on another side of the ventilator.

Problem: An ECRI Institute member hospital recently reported that staff responding to an audible alarm discovered that the breathing circuit support arm on a Servo-i ventilator had been positioned such that it compressed the breathing circuit at the inspiratory port. Although alarms suggested that patient flow was restricted, the cause was not immediately apparent, which prolonged troubleshooting of the problem. Hospital staff were unable to determine under what circumstances the arm had been moved into that position.

DISCUSSION

In the Servo-i's most common configuration— the mobile cart—the unit's support arm can be mounted in any of 4 vertical tracks; one track is on the ventilator's left side, another is on the right side, and 2 are on the rear. The arm can bend at any of 3 articulated joints and can also pivot horizontally around its base. By pivoting the bent arm and moving it up or down the tracks, the user can position the breathing circuit to accommodate the patient's needs (see Figure 1).

When the support arm is mounted on the same side as the ventilator's inspiratory and expiratory ports, there is the potential for it to occlude the inspiratory limb of the breathing circuit. If the arm is positioned low enough on the vertical track that its lowest articulating joint is below the height of the inspiratory port, pivoting the arm toward the ventilator could cause it to compress the breathing circuit against the port, potentially obstructing flow to the patient (see Figure 2).

If the arm is positioned high enough in the track that the joint is above the inspiratory port, the arm cannot compress the circuit. The problem is also avoided if the support arm is not mounted on the side of the ventilator where the ports are located. (In the cart configuration, the Servo-i can be purchased with the ports on either the right or the left side.)

ECRI Institute is not aware of any similar reports, which may suggest that the problem occurs rarely. Clinical staff would almost certainly detect the problem if it occurred when the patient was first placed on the ventilator. However, since the support arm can easily be moved intentionally or unintentionally (for instance, if another object is pressed against it), the problem could be introduced anytime the ventilator or the arm is moved by clinicians, other staff, or even visitors.

ECRI Institute Recommendations: ECRI Institute recommends that facilities using the cart-mounted Servo-i do the following:
(1) Direct respiratory care staff to, when possible, mount the breathing circuit support arm on a different side of the ventilator from the inspiratory port (this may not be feasible if doing so obstructs viewing of or access to the patient and the ventilator display).

(2) Instruct respiratory care staff that, if the support arm must be mounted on the same side as the inspiratory port, the arm should be positioned in the vertical track so that its lowest articulating joint is above the inspiratory port.

(3) Ensure that respiratory care staff verify that the Servo-i's alarm limits are

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appropriate for the patient. Proper setting of the high-peak-pressure and low-minute-volume alarms, in addition to being good clinical practice, should help alert staff if the problem occurs.

Source:

- ECRI Institute. Breathing circuit support arm on Maquet Servo-i ventilator may restrict gas flow to patient [hazard report]. *Health Devices* 2010 Oct;39(10):378-9.

Comment:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

- This Hazard Report has been adapted for inclusion in Health Devices Alerts. The original version of this article is available in the October 2010 issue of Health Devices.

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